

paragraph (this same paragraph was amended in Applicant's **Response to Official Action of December 19, 2000** and is being amended a second time):

*B1*

This application is a continuation-in-part of my co-pending application Serial No. 09/169,793, entitled PRODUCTION OF ssDNA *IN VIVO*, filed October 9, 1998, which is itself a continuation-in-part of application Serial No. 08/877,251, entitled STEM-LOOP CLONING VECTOR AND METHOD, filed June 17, 1997, now issued as Patent No. 6,054,299, and filed as a continuation application of application Serial No. 08/236,504, having the same title, filed April 29, 1994, now abandoned.

#### REMARKS

In the Official Action of June 15, 2001, certain informalities in the specification were noted and claims 1-7 were rejected under 35 U.S.C. 102(a) and (e) as being "clearly anticipated by any one of" the Mirochnitchenko, *et al.*, Miyata, *et al.*, or Inouye, *et al.* references. These rejections are respectfully traversed.

With regard to the alleged informalities in the specification, the application as filed was comprised of pages 1-30 of disclosure, the claims (all set out on page 31), an Abstract on page 32, and a table of sequences ("Table 1") on page 33. It is therefore apparent that, contrary to the allegations on the second page of the Action, page 32 is not missing from the specification and any objection based on that supposedly missing page is respectfully traversed. The Abstract that was set out on page 32 was set out on a separate page (and if that page had been missing from the specification, how could the first Office Action in this application have objected to it?), so that objection to the specification is also respectfully traversed. Note that the Abstract was amended in Applicant's **Response to Official Action of December 19, 2000** by referring to page 32 of the specification. Also, because Table 1 sets out a sequence ID for each sequence, and that sequence ID is repeated in the specification, Table 1 meets all of the requirements of 37 C.F.R. 1.821. Reconsideration and withdrawal of these several objections to the specification is respectfully requested.

As set out in Applicant's **Response to Official Action of December 19, 2000**, it is respectfully requested that the objection to the drawings be held in abeyance until the application is otherwise allowable. 37 C.F.R. 1.85(c), 1.111(b).

With regard to the objection to the cross-reference paragraph on page 1 of the specification, the amendment to the specification set out above should remedy both the objection as to the absence of a recitation of the status of Serial No. 08/236,504 and the requirement that the parentage of the present application be set out in a single sentence. Reconsideration and withdrawal of this objection to the specification is respectfully requested.

Turning now to the prior art rejections, although it is alleged in the Action that the cited references “clearly anticipate” the claims of the present application, it is not clear to Applicant that they anticipate the claims at all. The Rules of Practice require that

In rejecting claims for want of novelty . . . , the examiner must cite the best references . . . [and] when a reference is complex . . . that particular part relied upon must be designated as nearly as practicable.” 37 C.F.R. 1.106(b).

Although the Office Action cites, for instance, the “Results and Discussion” section of Mirochnitchenko, *et al.*, pages 4-10 of Miyata, *et al.*, and pages 5-14 of Inouye, *et al.*, in making these §102 rejections, there can be no doubt that the cited references are “complex.” Further, no attempt was made in the office Action to comply with the requirements of 37 C.F.R. 1.106(b) by pointing out “the particular part [of these references that was] relied upon” in making these rejections. The citation in the Action to nine pages of the Inouye, *et al.* European patent application and six pages of the Miyata, *et al.* U.S. patent, for instance, is no substitute for a rejection that follows the formula of “element A recited in Applicant’s claim 7 is disclosed at col. X, line Y of Inouye, *et al.*.”

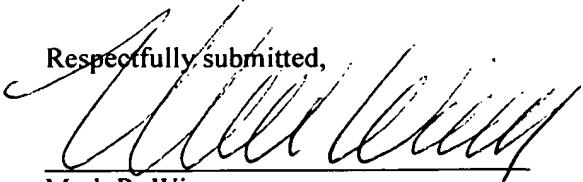
In short, it is Applicant’s contention that, because the Office bears the burden of establishing that Applicant is not entitled to a patent (§102 of the Statute states that “a person **shall** [emphasis added] be entitled to a patent unless” the Office can establish that the application does not meet the requirements of the Statute), that burden was not met by citing three complex references in the manner set out in the Action. Applicant therefore respectfully traverses this rejection and, if the rejection is renewed in a subsequent Action, respectfully requests that Applicant be given the opportunity to respond to this rejection, before the rejection is made final, so as to fully develop the issues in the application. MPEP §706.07.

Before any subsequent action is written, however, it is respectfully requested that it be noted that none of the cited references disclose a nucleic acid construct comprised of first and second sequences of interest as recited in the claims. Further, if none of the references disclose constructs with first and second sequences of interest, the cited references certainly cannot disclose constructs in which the sequences of interests are located in specific locations as recited in the claims. It is therefore respectfully submitted that it would be inappropriate to renew the §102 rejection of the claims over these prior references at all such that withdrawal of those rejections is appropriate at this time.

Entry of the above amendments, reconsideration and withdrawal of the §102 rejections, allowance of the claims, and passage of the application to issuance are all respectfully requested. In the unforeseen event that there are questions regarding this application, it is respectfully

requested that Applicant's counsel be contacted at the address and telephone number set out below.

Respectfully submitted,



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ATTORNEY FOR APPLICANT

Date: November 15, 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	§	Atty. Docket No.:	INGA,004/CIP
Charles A. Conrad	§		
Serial No.: 09/397,782	§	Examiner:	Martinell
Filed: September 16, 1999	§		
For: <b><i>IN VIVO PRODUCTION</i></b> <b>OF ssDNA USING REVERSE</b> <b>TRANSCRIPTASE WITH</b> <b>PREDEFINED REACTION</b> <b>TERMINATION VIA</b> <b>STEM-LOOP FORMATION</b>	§	Group Art Unit:	1633

COMMISSIONER OF PATENTS  
AND TRADEMARKS  
WASHINGTON, D.C. 20231

<b><u>CERTIFICATE OF MAILING (37 CFR 1.8a)</u></b>	
<p>I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date indicated below with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patent and Trademarks, Washington, D.C. 20231.</p>	
Nov. 15, 2001	
<p>Mark R. Wisner, Registration No. 30,603</p>	
Date	

**ATTACHMENT TO RESPONSE TO OFFICIAL  
ACTION OF JUNE 15, 2001 (37 C.F.R. 1.121)**

Dear Sir:

In accordance with the requirements of 37 C.F.R. 1.121, Applicant hereby respectfully submits versions of any replacement or added paragraphs, as well as any rewritten claims, on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of the paragraph(s) and/or claim(s):

The paragraph beginning at page 1, line 6 of the specification as filed (referring to the line numbers in the margin of the page) and ending on page 1, line 11 was amended in Applicant's **Response to Official Action of December 19, 2000**. That same paragraph (as amended) is being amended a second time as follows:

This application is a continuation-in-part of my co-pending application Serial No. 09/169,793, entitled PRODUCTION OF ssDNA *IN VIVO*, filed October 9, 1998[. Serial No. 09/169,793], which is itself a continuation-in-part of application Serial No. 08/877,251, entitled STEM-LOOP CLONING VECTOR AND METHOD, filed June 17, 1997, now issued as Patent No. 6,054,299[. Serial No. 08/877,251 is], and filed as a continuation application of application Serial No. 08/236,504, having the same title, filed April 29, 1994, now abandoned.

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